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Attorneys for Plaintiff
TERRY STATEN

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

TERRY STATEN, individually and on
behalf of other persons similarly
situated,

Plaintiff,

vs.

ASTELLAS PHARMA US, INC.;
SEAGEN, INC.; AGENSYS, INC.; and
DOES 1 THROUGH 100, inclusive,

Defendants.

Case No.: 2:23-cv-01898

CLASS ACTION COMPLAINT

- 1. STRICT LIABILITY –
FAILURE TO WARN**
- 2. NEGLIGENT FAILURE TO
WARN**
- 3. FRAUD**
- 4. NEGLIGENT
MISREPRESENTATION**

DEMAND FOR JURY TRIAL

Plaintiff, TERRY STATEN (“Plaintiff”) on behalf of himself, and all others
similarly situated, complains, and alleges as follows:

INTRODUCTION

1. This is a consumer class action lawsuit pursuant to Fed. R. Civ. P. Rule
23, seeking damages for Defendants’ failure to warn about the dangerous side effects

1 the prescription cancer drug, Padcev, has on those who use it.

2
3 **JURISDICTION AND VENUE**

4 2. This Court has jurisdiction over this action pursuant to diversity
5 jurisdiction under 28 U.S. Code §1332(a)(1). Plaintiff is a citizen of California.
6 Defendants, Astellas Pharma US, Inc. and Agensys, Inc. have their principal places of
7 businesses in Northbrook, Illinois. Defendant, Seagen, Inc. has its principal place of
8 business in Bothell, Washington.
9

10 **PARTIES**

11
12 3. Plaintiff, Terry Staten, is an adult individual who resides in Santa Barbara,
13 California. Within the statute of limitations for the claims made herein, Plaintiff
14 suffered from Steven-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN)
15 as a result of taking Padcev, a prescription medication developed and manufactured by
16 Defendants.
17

18 4. Plaintiff appears in this action on behalf of himself and on behalf of all
19 others similarly situated.
20

21 5. Plaintiff is informed and believes and thereon alleges that Defendants,
22 Astellas Pharma US, Inc., Seagen, Inc., Agensys, Inc., and DOES 1 through 20
23 (hereinafter “Astellas”) developed and manufactured Padcev, a prescription drug
24 marketed to treat cancer found in the bladder.
25

26 6. Plaintiff is informed and believes that DOES 1 through 100 are
27 corporations, individuals, limited liability partnerships, limited liability companies,
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1 general partnerships, sole proprietorships or are other business entities or organizations
2 of a nature not currently known to Plaintiff.

3
4 7. Plaintiff is unaware of the true names of Defendants DOES 1 through 100.
5 Plaintiff sues said Defendants by said fictitious name and will amend this complaint
6 when the true names and capacities are ascertained or when such facts pertaining to
7 liability are ascertained, or as permitted by law or by the Court. Plaintiff is informed
8 and believe that each of the fictitiously named Defendants is in some manner
9 responsible for the events and allegations set forth in this Complaint.
10

11
12 8. Plaintiff is informed and believes and based thereon alleges that at all
13 relevant times, each Defendant was an employer, was the principal, agent, partner, joint
14 venture, officer, director, controlling shareholder, subsidiary affiliate, parent
15 corporation, successor in interest and/or predecessor in interest of some or all of the
16 other Defendants, and was engaged with some or all of the other Defendants in a joint
17 enterprise for profit and bore such other relationships to some or all of the other
18 Defendants so as to be liable for their conduct with respect to the matters alleged in this
19 complaint. Plaintiff is further informed and believe and thereon allege that each
20 Defendant acted pursuant to and within the scope of the relationships alleged above,
21 and that at all relevant times, each Defendant knew or should have known about,
22 authorized, ratified, adopted, approved, controlled, aided and abetted the conduct of all
23 other Defendants. As used in this Complaint “Defendant” means “Defendants and each
24 of them,” and refers to the Defendants named in the particular cause of action and
25
26
27
28

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1 DOES 1 through 100.

2 9. At all times mentioned herein, each Defendant was the co-conspirator,
3 agent, servant, employee, and/or joint venture of each of the other Defendants and was
4 acting within the course and scope of said conspiracy, agency, employment, and/or
5 joint venture and with the permission and consent and knowledge of each of the other
6 Defendants.
7
8

9 **FACTS COMMON TO ALL CAUSES OF ACTION**

10 10. Padcev purports to assist in treating adults with bladder cancer in an effort
11 to lengthen their life expectancy. Yet, Defendants failed to warn Plaintiff and its other
12 users of the serious side effects to the skin that can occur when taking Padcev.
13

14 11. SJS and TEN are serious skin reactions that can be fatal, causing patient
15 deaths in some situations. In the initial Padcev drug label there was a warning about
16 general, low-level Padcev skin side effects in the Warnings and Precautions section.
17

18 12. In or around March of 2021, the first Padcev label change occurred
19 wherein Defendants added warnings for skin side effects of SJS and TEN.
20

21 13. However, in July of 2021, the U.S. Food and Drug Administration (FDA)
22 mandated increased warnings about Padcev skin side effects SJS and TEN in the form
23 of “black box” warnings with the bolded title “**WARNING: SERIOUS SKIN**
24 **REACTIONS**”.
25

26 14. Mr. Staten was diagnosed with bladder cancer. He was 77 years old at the
27 time. He received medical care from a hematology oncologist named Julian Davis,
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1 M.D. from Ridley Tree Cancer Center and then out of UCLA Santa Barbara Cancer
2 Care.

3
4 15. Dr. Davis first prescribed Keytruda to Mr. Staten and it did not work the
5 way Dr. Davis had anticipated. Thus, Dr. Davis prescribed Mr. Staten Padcev. Mr.
6 Staten's insurance approved the prescription on June 16, 2021. His first injection of
7 the drug occurred on June 29, 2021; second dose on July 6, 2021; third dose on July
8 13, 2021; fourth dose on July 27, 2021; fifth dose on August 3, 2021; and sixth dose
9 on August 10, 2021.

10
11
12 16. On August 17, 2021, Mr. Staten laid down in bed and had difficulty
13 breathing. He began to feel severe pain to his entire body because his skin felt like it
14 was as burning. 911 was called and Mr. Staten was rushed to Santa Barbara Cottage
15 Hospital. Mr. Staten spent five weeks in the medical intensive care unit (MICU) and
16 three more weeks at Cottage Hospital. Mr. Staten was then transferred to Buena Vista
17 Care Center in Santa Barbara.

18
19
20 17. As a result of taking Padcev, Mr. Staten's skin experienced necrosis.
21 Necrosis occurs when too little blood flows to the tissue. Mr. Staten had painful rashes
22 that spread, blistered, and peeled. He also lost approximately 62 lbs. over this eight-
23 week span of time.

24
25 18. After advising Dr. Davis about these adverse skin reactions, Dr. Davis
26 discontinued Mr. Staten prescription of Padcev.
27
28

1 **CLASS DEFINITIONS AND CLASS ALLEGATIONS**

2 19. Plaintiff brings this action on behalf of himself and on behalf of all other
3
4 similarly situated persons as a class action pursuant to Fed. R. Civ. P. Rule 23. The
5 members of the Class are defined as follows:

6 All persons residing in the United States and its Territories who, during
7 the period beginning two (2) years prior to the filing of this Complaint
8 and continuing through the date of resolution of this case, that took the
9 prescription drug PADCEV and were harmed.

10 20. This action has been brought and may be properly maintained as a class
11 action pursuant to the provisions of Fed. R. Civ. P. Rule 23 and other applicable law.

12 21. **Numerosity of the Classes:** Members of the class are so numerous that
13 their individual joinder is impracticable. Plaintiff estimates that there are no less than
14 1,000 persons in the identified class. The precise number of class members and their
15 addresses are unknown to Plaintiff. However, Plaintiff is informed and believes and
16 thereon alleges that the number can be obtained through Defendants' records of who
17 Padcev was sent to for use then those records of the patients that were prescribed
18 Padcev. Class members may be notified of the pendency of this action by conventional
19 mail, electronic mail, the Internet, or published notice.

20 22. **Existence of Predominance of Common Questions of Fact and Law:**
21 Common questions of law and fact exist as to all members of the class. These questions
22 predominate over any questions effecting only individual members of the class. These
23 common factual and legal questions include:
24
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26
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1 (a) Whether Defendants knew of the potential skin reaction side effects
2 that occurred to people who used Padcev;

3
4 (b) Whether the skin reaction side effects posed a substantial danger when
5 Padcev was used;

6 (c) Whether ordinary consumers would not have recognized the potential
7 skin reaction side effects of Padcev;

8
9 (d) Whether Defendants failed to warn of the potential skin reaction side
10 effects;

11
12 (e) Whether Defendants raise any affirmative defenses that are
13 universal in application.

14 23. **Typicality**: Plaintiff's claims are typical of the claims of the members of
15 the class, which all arise from the same operative facts and are based on the same legal
16 theories.

17
18 24. **Adequacy**: Plaintiff will adequately and fairly protect the interests of the
19 members each of the class. Plaintiff has no interest adverse to the interests of absent
20 class members. Plaintiff is represented by legal counsel who has substantial class action
21 experience in civil litigation.

22
23
24 25. **Superiority**: A class action is superior to other available means for fair
25 and efficient adjudication of the claims of the class and would be beneficial for the
26 parties and the court. Class action treatment will allow a large number of similarly
27 situated persons to prosecute their common claims in a single forum, simultaneously,
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efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would require. The monetary amounts due to many individual class members are likely to be relatively small, and the burden and expense of individual litigation would make it difficult or impossible for individual members of each class to seek and obtain relief. A class action will serve an important public interest by permitting such individuals to effectively pursue recovery of the sums owed to them. Further, class litigation prevents the potential for inconsistent or contradictory judgments raised by individual litigation.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN
(By Plaintiff and the Class against all Defendants)

26. Plaintiff incorporates paragraphs 1 through 25 of this complaint as though fully alleged herein.

27. Padcev was developed and manufactured by Defendants. At the time that Padcev was manufactured, Defendants knew that consumers that used Padcev could have dangerous skin reaction side effects similar to that of SJS and TEN. Nonetheless, Defendants failed to adequately warn Plaintiff and those similarly situated of such skin reaction side effects.

28. Plaintiff, and those similarly situated took Padcev. The lack of sufficient warnings was a substantial factor in causing Plaintiff and other putative class members' harm.

///

SECOND CAUSE OF ACTION
NEGLIGENT FAILURE TO WARN
(By Plaintiff and the Class against all Defendants)

29. Plaintiff incorporates paragraphs 1 through 28 of this complaint as though fully alleged herein.

30. As alleged herein above, Padcev was developed and manufactured by Defendants. At the time that Padcev was manufactured, Defendants knew that consumers that used Padcev could have dangerous skin reaction side effects similar to that of SJS and TEN. Nonetheless, Defendants failed to adequately warn Plaintiff and those similarly situated of such skin reaction side effects. Plaintiff and the putative class members are informed and believe and thereon allege that a reasonable manufacturer, distributor, or seller of Padcev would have adequately warned consumers of the dangerous skin reaction side effects of Padcev.

31. Plaintiff, and those similarly situated took Padcev. The lack of sufficient warnings was a substantial factor in causing Plaintiff and other putative class members' harm.

THIRD CAUSE OF ACTION
FRAUD - CONCEALMENT
(By Plaintiff and the Class against all Defendants)

32. Plaintiff incorporates paragraphs 1 through 31 of this complaint as though fully alleged herein.

33. Plaintiff is informed and believes and thereon alleges that at the time Defendants developed, manufactured, and sold Padcev to the public, they knew that

1 the skin reaction side effects while taking Padcev were dangerous. Nonetheless,
 2 Defendants failed to warn the general public about it. These omissions were a
 3 substantial factor in causing harm to Plaintiff and the putative class members.
 4

5 **FOURTH CAUSE OF ACTION**
 6 **NEGLIGENT MISREPRESENTATION**
 7 **(By Plaintiff and the Class against all Defendants)**

8 34. Plaintiff incorporates paragraphs 1 through 33 of this complaint as though
 9 fully alleged herein.

10 35. Plaintiff alleges, in the alternative, that the concealment of material facts
 11 set forth herein above by Defendants were done negligently and recklessly,
 12 proximately resulting in injuries and damages to Plaintiff and the putative class
 13 members.
 14

15 **PRAYER FOR RELIEF**

16 WHEREFORE, Plaintiff on behalf of himself and all others similarly situated,
 17 pray for relief and judgment against Defendant as follows:
 18

- 19 1. That this action be certified as a class action pursuant to Fed. R. Civ. P.
 20 Rule 23;
 21
- 22 2. That judgment be entered for Plaintiff and the class against Defendants
 23 for damages;
 24
- 25 3. That judgment be entered for Plaintiff and the class against Defendants
 26 for punitive damages for committing fraud;
 27

1 4. That the Court award prejudgment and post-judgment interest at the
2 maximum legal rate;

3
4 5. That the Court award attorneys' fees;

5 6. That the Court awarding cost of suit herein; and

6 7. All such other and further relief as the Court deems just.
7
8

9 Date: March 14, 2023

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11 By: *Evan Selik*
12 EVAN SELIK
13 CHRISTINE C. ZAOUK
14 Attorneys for Plaintiff,
15 TERRY STATEN
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DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for himself and the Class on all claims so triable.

Date: March 14, 2023

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